

K081158

510(k) SUMMARY

JUL - 3 2008

Zodiac® Polyaxial Spinal Fixation System
510(k) SUMMARY
APRIL 2008

Company: Alphatec Spine, Inc.
2051 Palomar Airport Road#100
Carlsbad, CA 92011 USA
Direct: (760) 494-6770
Fax: (760) 431-9132

Contact Person: Cheryl Allen, Regulatory Affairs Specialist

Trade/Proprietary Name: Zodiac® Polyaxial Spinal Fixation System

Common Name: Pedicle Screw Spinal Device

Classification Names: Spinal Interlaminar Fixation Orthosis
Pedicle Screw Spinal System

Classification Number(s)/Product Code(s): 21 CFR 888.3050, 888.3070
KWP, MNI, MNH

Product Description:

The Zodiac® Polyaxial Spinal Fixation System is intended for use as a posterior spinal fixation device to aid in the surgical correction of various spinal deformities and pathologies in the thoraco-lumbo-sacral iliac portion of the spine. It is intended to provide stabilization during the development of fusion utilizing a bone graft. Specific indications for the Zodiac® Polyaxial Spinal Fixation System are dependent in part on the configuration of the assembled device and the method of attachment to the spine.

The intended use and indications for use of the modified device, as described in its labeling, has not changed as a result of the additional components.

Indications for Use:

It is intended that this device, in any system configuration, be removed after development of solid fusion mass. Hook component indications are limited to T7-L5. Sacral-iliac screw indications are limited to the sacrum-iliac crest only.

1. The Zodiac® Polyaxial Spinal Fixation System, when used as a hook and sacral iliac screw fixation system (nonpedicle screw) is intended for:
 - a. Patients having fractures of the thoracic and lumbar spine,

- b. Patients having deformity (i.e. idiopathic scoliosis, neuromuscular scoliosis or kyphoscoliosis with associated paralysis or spasticity,
- c. Patients having spondylolisthesis (i.e. isthmic spondylolisthesis, degenerative spondylolisthesis, and acute pars fracture allowing spondylolisthesis).

2. The Zodiac® Polyaxial Spinal Fixation System, when used as a pedicle screw system in the thoraco-lumbo-sacral iliac region of the spine is intended for degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor and failed previous fusion (pseudoarthrosis).

3. The Zodiac® Polyaxial Spinal Fixation System, when used as a pedicle screw system is intended for:

- a. Patients receiving only autogenous bone graft
- b. Patient having the device fixed or attached to the lumbar and sacral iliac spine and having severe spondylolisthesis grade 3 or 4 at the fifth lumbar-first sacral (L5-S1) vertebral joint.

4. The Zodiac® Polyaxial Spinal Fixation System, when used as a laminar hook and bone screw system is intended for:

- a. Patients having fractures of thoracic and lumbar spine.
- b. Patients having thoracolumbar deformity (i.e. idiopathic scoliosis, neuromuscular scoliosis, kyphoscoliosis or kyphoscoliosis with associated paralysis or spasticity.
- c. Patients having spondylolisthesis (i.e. Isthmic spondylolisthesis, degenerative spondylolisthesis and acute pars fracture allowing spondylolisthesis).

Substantial Equivalence:

The Zodiac® Polyaxial Spinal Fixation System additional components is substantially equivalent to the following predicate device:

<u>Trade/Proprietary/Model Name</u>	<u>Manufacturer</u>	<u>510(k) No.</u>
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K033090
Zodiac® Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K042673
Zodiac® Stainless Steel Spinal Fixation System	Alphatec Spine, Inc.	K051286
Zodiac® 4.0 Polyaxial Spinal Fixation System	Alphatec Spine, Inc.	K071890

Performance Data:

The mechanical performance of the Zodiac® Polyaxial Spinal Fixation System additional components is substantially equivalent to the predicate Zodiac® Polyaxial Spinal Fixation System device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Alphatec Spine, Inc.
% Ms. Paula Morgan
Director, Regulatory Affairs
2051 Palomar Airport Road
Carlsbad, CA 92011

JUL - 3 2008

Re: K081158
Trade/Device Name: Zodiac™ Polyaxial Spinal Fixation System
Regulation Number: 21 CFR 888.3070
Regulation Names: Pedicle screw spinal system
Regulatory Class: II
Product Code: MNH, MNI, KWP
Dated: June 25, 2008
Received: June 26, 2008

Dear Ms. Morgan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Paula Morgan

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a long horizontal flourish extending to the right.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K081158

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Concurrence of CDRH, Office of Device Evaluation (ODE)

4. The Zodiac® Polyaxial Spinal Fixation System, when used as a laminar hook and bone screw system is intended for:

- a. Patients having fractures of thoracic and lumbar spine.
- b. Patients having thoracolumbar deformity (i.e. idioscoliosis, neuromuscular scoliosis, kyphoscoliosis or kyphoscoliosis with associated paralysis or spasticity.
- c. Patients having spondylolisthesis (i.e. Isthmic spondylolisthesis, degenerative spondylolisthesis and acute pars fracture allowing spondylolisthesis).

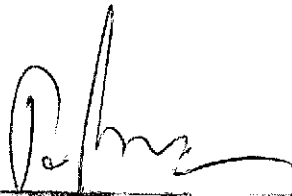
Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number

1208115K